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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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DICKSTEIN SHAPIRO MORIN & OSHINSKY LLP			KIM, JOHN	
2101 L Street, NW			ART UNIT	
Washington, DC 20037			PAPER NUMBER	
			3733	

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Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/803,044	Applicant(s) SCHMIEDING ET AL.	
	Examiner John Kim	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
 4a) Of the above claim(s) 12 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/18/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, 4-11, drawn to method of forming a socket and knee reconstruction, classified in class 606, subclass 88.
- II. Claim 12, drawn to a marking hook, classified in class 433, subclass 143.
- III. Claim 13, drawn to a drill guide, classified in class 606, subclass 96.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process can be performed with other tools or by hand.

Inventions I and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process can be performed with other tools or by hand.

Inventions III and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP §

806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because a "marking hook" is not particularly required as part of the drill guide. The subcombination has separate utility such as a dental tool.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Stephen Soffen on January 25, 2006 a provisional election was made without traverse to prosecute the invention of I, claims 1-11. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12-13 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

Examiner notes that one of the references (Schmieding et al. – US Pat 5350716, published Sept. 1999) could not be found. Both the patent number and the publishing date are incorrect when associated with the inventor. Thus, it was not considered.

Drawings

The drawings were received on June 3, 2004. These drawings are acceptable.

Double Patenting

The provisional nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4, 5, and 9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9, 15 and 21 of copending Application No. 10/792780. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the application claims and the patent claims lies in the fact that the patent claims include more elements and are thus much specific. Thus the invention of the patent claims are in effect a "species" of the "generic" invention of the application claims. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since the application claims are anticipated by the patent claims, they are not patentably distinct from the patent claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

Claims 7, 8, 10 are objected to because of the following informalities: Applicant states "pin" several times. For examination purposes, examiner will take note that "pin" refers to "guide pin" at this time. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6, which depends from claim 4, recites the limitation "step of introducing a guide pin" in line 1-2. There is insufficient antecedent basis for this limitation in the claim. Examiner takes note that this step is found in claim 5 and for examination purpose claim 6 depends from claim 5.

Claim 11, which depends from claim 4) recites the limitation "step of aligning the guide pin" in line 1-2. There is insufficient antecedent basis for this limitation in the claim. Examiner takes note that this step is found in claim 7 and for examination purpose claim 11 depends from claim 7.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (US Pat 6149654, in IDS) in view of McGuire et al. (US Pat 5374270).

Johnson discloses a method comprising the steps of introducing a guide pin through a bone and inserting a cutter at the distal end, securing the cutter, and drilling into the bone in a retrograde manner using the guide pin. (Johnson col 2:24-49, fig 4a-

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4g) Johnson fails to teach of having a cannulated cutter. McGuire teaches of having a cannulated drill bit (11) or cutter (McGuire col 3:18-24), which solves the problem of easy removal of the cutter while leaving a pin in place (col 2:18-25). It would have been obvious to one skill in the art at the time the invention was made to perform the method of Johnson with a cannulated cutter in view of McGuire et al. in order to solve the problem of easy removal of the cutter while leaving a pin in place.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (US Pat 6149654, in IDS) in view of McGuire et al. (US Pat 5374270) as applied to claim 1 above, and further in view of Purnell et al (US Pat 4781182).

The combination of Johnson and McGuire discloses the claimed method steps except for aligning the guide pin with a drill guide and a marking hook. Purnell teaches of using a drill guide (2), a marking hook (26, 28, or 30) (col 2:27-28), and where the guide pin enters the "pin sleeve" (14) (see fig 1). (col 6: 15-18, 25-31, 33-41). Using a drill guide facilitates the determination of the isometric cruciate ligament points of femoral origin for anterior cruciate ligament reconstruction (col 1:29-64). It would have been obvious to one skill in the art at the time the invention was made to perform the method of the combination of Johnson as modified by McGuire, including a drill guide in view of Purnell et al., in order to determine the proper location of the isometric cruciate ligament points.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (US Pat 6149654, in IDS) in view of McGuire et al. (US Pat 5374270) and Purnell et al (US Pat 4781182) as applied to claim 2 above, and further in view of Urban (US Pat 5676544).

The combination of Johnson, McGuire, and Purnell discloses the claimed method except for having a marking hook with a tip and a visible mark 5 mm proximal to the tip. Urban teaches of having a marking hook that has a hook (210), a tip (220) and a visible mark (240) 5 mm proximal to the tip (see fig 2) (col 6:36-50). This allows a user to have an accurate measurement (col 2:49-54). It would have been obvious to one skill in the art at the time the invention was made to perform of the combination of Johnson as modified by McGuire and Purnell, including a marking hook with a visible mark 5 mm proximal to the tip in view of Urban, in order to provide the user with accurate measurement.

Claims 4, 5, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (US Pat 6149654, in IDS) in view of Morgan et al. (US Pat 5603716, in IDS).

Johnson discloses of method comprising the steps of forming a socket in bone of a joint in a retrograde manner (claim 4). Johnson discloses the step of forming a socket in the bone by introducing a guide pin through the bone and attach a retrograde cutter, and retrograde cutting to form a socket (Johnson col 2:24-49, fig 4a-4g) (claim 5 and 9). Johnson fails to teach in specificity the surgery site as the knee and to secure the

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ends of a graft to the socket. Morgan teaches of forming sockets in the femur and tibia and fixating the graft in the socket (col 1:45-2:31). This method simplifies ACL reconstruction in comparison to previous methods and reduces morbidity (col 1:39-44). It would have been obvious to one skill in the art at the time the invention was made to perform the method of the combination of Johnson to include forming sockets in the femur and tibia and fixating the graft in the sockets in view of Morgan in order to simplify ACL reconstruction in comparison to previous methods and reduce morbidity.

Claims 6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (US Pat 6149654, in IDS) and Morgan et al. (US Pat 5603716, in IDS) as applied to claim 4 above, and further in view of Purnell et al. (US Pat 4781182).

The combination of Johnson and Morgan discloses the claimed method except for the step of introducing the guide pin using a drill guide and an offset marking hook. Purnell teaches of using a drill guide (2), a marking hook (26, 28, or 30) (col 2:27-28), and where the guide pin enters the "pin sleeve" (14) (see fig 1). (col 6: 15-18, 25-31, 33-41). Using a drill guide facilitates the determination of the isometric cruciate ligament points of femoral origin for anterior cruciate ligament reconstruction (col 1:29-64). It would have been obvious to one skill in the art at the time the invention was made to perform the method of the combination of Johnson modified by Morgan, including a drill guide in view of Purnell, in order to determine the proper location of the isometric cruciate ligament points.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (US Pat 6149654, in IDS), Morgan et al. (US Pat 5603716, in IDS), and Purnell et al. (US Pat 4781182) as applied to claims 6 above, and further in view of Urban (US Pat 5676544).

The combination of Johnson, Morgan, and Purnell discloses the claimed method except for having a marking hook with a tip and a visible mark 5 mm proximal to the tip. Urban teaches of having a marking hook that has a hook (210), a tip (220) and a visible mark (240) 5 mm proximal to the tip (see fig 2) (col 6:36-50). This allows a user to have an accurate measurement (col 2:49-54). It would have been obvious to one skill in the art at the time the invention was made to perform of the combination of Johnson as modified by Morgan and Purnell, including a marking hook with a visible mark 5 mm proximal to the tip in view of Urban, in order to provide the user with accurate measurement.

Claims 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (US Pat 6149654, in IDS) and Morgan et al. (US Pat 5603716, in IDS) as applied to claims 5 and 9 above, and further in view of McGuire et al. (US Pat 5374270).

The combination of Johnson and Morgan discloses the claimed method except for having a cannulated guide pin. McGuire teaches of having a cannulated drill bit (11) or guide pin (McGuire col 3:18-24), which solves the problem of easy removal of the cutter while leaving a pin in place (col 2:18-25). It would have been obvious to one skill in the art at the time the invention was made to perform the method of the combination

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of Johnson as modified by Morgan, including a cannulated guide pin in view of McGuire, in order to solve the problem of easy removal of the cutter while leaving a pin in place.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (571) 272-2817. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JK 


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER